



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**42 CFR Parts 400, 410, 414, 415, 423, 424, and 425**

**[CMS-1734-F2]**

**RIN 0938-AU10, 0938-AU31, 0938-AU32, and 0938-AU33**

**Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19; Correcting Amendment**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule and interim final rule; correcting amendment.

**SUMMARY:** This document corrects a typographical error in the final rule that appeared in the December 28, 2020 **Federal Register** (hereinafter referred to as the CY 2021 PFS final rule). The effective date was January 1, 2021.

**DATES:** Effective date: This correcting amendment is effective [insert date of publication in the **Federal Register**].

Applicability date: The correction indicated in this document is applicable beginning January 1, 2021.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Lambert Lawson, (410) 786-1366, Gaysha Brooks, (410) 786-9649, or Annette Brewer, (410) 786-6580.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

In FR Doc. 2020-26815 of December 28, 2020, the CY 2021 PFS final rule (85 FR 84472), there was a typographical error that is identified and corrected in the regulation text of this correcting amendment. The correction is applicable as of January 1, 2021.

### **II. Summary of Error in the Regulations Text**

On page 85033 of the CY 2021 PFS final rule, we made a typographical error in amendatory instruction 24b for the regulation text of § 414.1400(b)(2) introductory text. In this amendatory instruction, we inadvertently noted that we were revising paragraph (b)(2) introductory text instead of adding it. Accordingly, we are revising amendatory instruction 24b to accurately reflect the addition of paragraph (b)(2) introductory text.

### **III. Waiver of Proposed Rulemaking and Delay in Effective Date**

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (the APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and

delay in effective date requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons for it in the rule. In addition, section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting amendment does not constitute a rulemaking that would be subject to these requirements. This document merely corrects a typographical error in the CY 2021 PFS final rule. The correction contained in this document is consistent with, and does not make substantive changes to, the policies and payment methodologies that were proposed, subject to notice and comment procedures, and adopted in the CY 2021 PFS final rule. As a result, the correction made through this correcting amendment is intended to resolve a typographical error so that the CY 2021 PFS final rule accurately reflects the policies adopted in the final rule. Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the CY 2021 PFS final rule or delaying the effective date of the corrections would be contrary to the public interest because it is in the public interest to ensure that the rule accurately reflects our policies as of the date they take effect. Further, such procedures would be unnecessary because we are not making any substantive revisions to the final

rule, but rather, we are simply correcting the **Federal Register** document to reflect the policies that we previously proposed, received public comment on, and subsequently finalized in the CY 2021 PFS final rule. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

#### **List of Subjects in 42 CFR Part 414**

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendments to part 414:

#### **PART 414--PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES**

1. The authority citation for part 414 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395hh, and 1395rr(b)(1).

2. Amend §414.1400 by revising the heading of paragraph (b)(2) and adding paragraph (b)(2) introductory text to read as follows:

##### **§414.1400 Third party intermediaries.**

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(b) \*\*\*

(2) QCDR conditions for approval. In addition to the other requirements in this section, the criteria for an entity to be approved as a QCDR include the following:

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Dated: February 9, 2021.

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**Wilma M. Robinson,**

Deputy Executive Secretary to the Department,

Department of Health and Human Services.

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